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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Falder, *et al.*	)	Group Art Unit: 1616
Serial No.: 10/039,677	)	Examiner: Alton N. Pryor
Filed: January 4, 2002	)	Deposit Account: 50-2548
For: Anti-Microbial Composition	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S REPLY BRIEF TO EXAMINER'S ANSWER

Dear Sir:

Applicant submits the present Reply Brief in accordance with 37 C.F.R. § 41.41. The Examiner's Answer has a mailing date of October 28, 2008, making the present Reply Brief due on or before December 28, 2008. This Reply Brief is being deposited as First Class Mail on the date noted on the attached Certificate of Mailing and is believed to be timely filed. The present Reply Brief is intended to be responsive to each and every new issue raised in the Examiner's Answer. Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Arguments

The Examiner's Answer is based upon a fundamentally incorrect understanding of the claimed invention as compared with the cited art. This misunderstanding is then followed by an improper legal analysis. These errors of fact and law render the Examiner's position erroneous.

First, throughout the Examiner's Answer, he refers to the compound taught in Trinh as "dimethyl polysiloxane." As previously stated, Trinh does not teach the use of "dimethyl polysiloxane" or polydimethylsiloxane. Trinh teaches the use of "polyalkylene oxide polysiloxanes having a dimethyl polysiloxane hydrophobic moiety and one or more hydrophilic polyalkylene side chains." Trinh, col. 11, lines 48 – 51 (emphasis added). Polyalkylene oxide polysiloxanes are not dimethyl polysiloxanes or polydimethylsiloxanes, as asserted by the Examiner. *See* Applicant's Appeal Brief, p. 8-9. The Examiner's terminology is incorrect and misleading.

In addition to misunderstanding the differences between the compounds used in the invention and those of Trinh, the Examiner also mischaracterizes their relationship. In particular, the Examiner asserts that the polyalkylene oxide polysiloxanes of Trinh are structurally similar to the polydimethylsiloxane used in the compositions claimed by Applicant and that the two compounds are chemical homologs. Examiner's Answer, p. 6. These assertions are chemically incorrect.

The Trinh compounds and the claimed polydimethylsiloxane are not homologs, as argued by the Examiner. As is well known in the art, a homolog is "a compound belonging to a series of compounds differing from each other by a repeating unit, such as a methylene group, a peptide residue, etc." *Glossary of Terms Used in Medicinal*

Chemistry, International Union of Pure and Applied Chemistry (IUPAC), Chemistry and Human Health Division, available at http://www.chem.qmul.ac.uk/iupac/medchem/ (1998). Similarly, the MPEP defines homologs as "compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH_2- groups." MPEP § 2144.09.

Based upon this definition, the Examiner's argument is in error. Specifically, the Trinh polyalkylene oxide polysiloxane is not comprised of mere repeating units of polydimethylsiloxane. In fact, the Trinh polyalkylene oxide polysiloxane does not contain any repeating units of polydimethylsiloxane. It merely contains a single "dimethyl polysiloxane hydrophobic moiety and one or more hydrophilic polyalkylene side chains." Trinh, col. 11, lines 48 – 51 (emphasis added). Merely having a dimethyl polysiloxane moiety does not equate to homology. Further, the Trinh compound has "one or more hydrophilic polyalkylene side chains," indicated as R^1 groups, which completely destroy any homology that may have existed. In fact, Trinh actually requires that "[e]ach polyalkylene oxide polysiloxane has at least one R^1 group being a poly(ethyleneoxide/propyleneoxide) copolymer." Trinh, col. 12, lines 8-10. The Examiner's arguments that the Trinh compound comprises repeating units of polydimethylsiloxane, or that the two compounds are homologs of one another, are chemically incorrect. The compound of Trinh is simply not structurally similar to the polydimethylsiloxane used in the claimed compositions.

Even if the compounds were homologs of one another, which they are not, such a showing alone would not be sufficient to provide a *prima facie* case of obviousness. The Examiner argues that "in the absence of unexpected results, homologs are obvious

over one another." Examiner's Answer, p. 6. This is legally incorrect in this case based on the differences between the compounds. Instead, "homologs which are far removed from adjacent homologs may not be expected to have similar properties." MPEP § 2144.09 (citing *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960)). Further, homology is just one factor that must be considered with all other relevant facts in determining the issue of obviousness. *Id.* In fact, "[h]omology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed 'as a whole.'" *Id.* (citing *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972)).

In this case, the claimed polydimethylsiloxane is not a homolog of the polyalkylene oxide polysiloxane disclosed in Trinh. Even if it were a homolog, however, the claimed invention must be considered as a whole. *Id.* In such a consideration, the physical properties of the two compounds must be given substantial weight. As explained below, the physical properties of the two compounds are so different that substitution of polyalkylene oxide polysiloxane for polydimethylsiloxane in the present invention would destroy the intended function of the invention.

The polyalkylene oxide polysiloxanes of Trinh comprise both hydrophobic and hydrophilic moieties and must be water dispersible or water soluble: "the number of ethyleneoxy units ($-C_2H_4O$) in the polyether chain (RI) must be sufficient to render the polyalkylene oxide polysiloxane water dispersible or water soluble." Trinh, col. 12, lines 36-39. In contrast, the polydimethylsiloxanes of the present invention are entirely hydrophobic and are not water dispersible or water soluble. *See Merck Index* 3260 (Susan Dudavari, ed., 12th ed., Merck & Co., Inc. 1996) (Dimethylpolysiloxane is

"immiscible with water."). This difference in the physical properties of the compounds is extremely significant to the intended function of the claimed invention. As Applicant has previously illustrated in the Declaration of Dr. Ulrich Schwartz and Annexes I and II (submitted herewith in the "Evidence Appendix"), the claimed compositions have advantageous and unexpected anti-microbial properties, particularly in terms of residual effect. This residual effect could not be achieved if the hydrophobic polydimethylsiloxane were replaced by a water-soluble or water-dispersible component that has both hydrophilic and hydrophobic moieties.

In the compositions of the present invention, there is an interaction between the anti-microbial agent(s) and the low surface tension material. As an example, when polydimethylsiloxane is the low surface tension material, it holds the anti-microbial agent(s) on the surface to which the composition is applied even if that surface is subsequently wetted or washed. If the hydrophobic polydimethylsiloxane were replaced by a water-soluble or water-dispersible material having both hydrophilic and hydrophobic moieties, this residual effect simply would not be achieved because the polyalkylene oxide polysiloxane would not interact with the anti-microbial agent to retain the anti-microbial agent on the surface. Instead, washing the surface would effectively remove the polyalkylene oxide polysiloxane and the anti-microbial agent from the surface. Such compositions would not exhibit the residual anti-microbial effect exhibited by the compositions of the invention. Thus, substitution of the polyalkylene oxide polysiloxane of Trinh for the polydimethylsiloxane of the invention would destroy the intended function of the inventive composition. As such, the Examiner's argument that Applicant provided "no showing" of how Trinh's polyalkylene oxide polysiloxanes would

affect the properties of the claimed antimicrobial composition differently from polydimethylsiloxane is incorrect. Examiner's Answer, p. 6.

A *prima face* case of obviousness has not been presented in this case. However, even if a *prima face* case had been made based upon structural similarities, "[t]he presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds." MPEP § 2144.09 (citing *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)). In this case, there is no reasonable expectation that the polyalkylene oxide polysiloxane taught by Trinh would provide the necessary hydrophobicity needed to accomplish the function of the present invention. Accordingly, the teachings of Trihn do not make the present invention obvious.

In a separate flawed argument, the Examiner asserts that "the claim recites polydimethylsiloxanes broadly which makes any compound having a dimethylsiloxane group an obvious species falling within the polydimethylsiloxane genus." Examiner's Answer, p. 6. The claims of the present invention recite, in part, "at least one compound having a low surface tension of from 8 to 14 mN/m, and selected from the group consisting of silanes, soya lecithins, polydimethylsiloxanes, polydimethylhydroxysiloxanes, and mixtures thereof." The term "polydimethylsiloxanes" is used in its plural form because the compound, $(CH_3)_3$-Si-O-$(Si(CH_3)_2$-$O)_n$-$Si(CH_3)_3$, may have more than one embodiment based upon the numbers of repeating monomer ($SiO(CH_3)_2$) units, indicated by subscript "n". Thus, if polydimethylsiloxanes are considered a genus, each embodiment based upon different numbers of repeating

monomer units would be considered the species of that genus. In contrast, every compound having a dimethylsiloxane moiety would not be considered a species of that genus. Thus, the polyalkylene oxide polysiloxanes of Trinh would not be a species of polydimethylsiloxanes and would not make the present invention obvious, and the Examiner's argument to the contrary must fail.

Lastly, the Examiner admits that Applicant has provided unexpected results for the compositions stated in Dr. Schwarz's declaration, but asserts that the claims are not commensurate in scope with the declaration. However, in this case, four different compositions that fall within the scope of the claims were tested at many different concentrations and each provided unexpected results. This illustrates that the compositions tested in this case were representative of the entire class of compositions and provide an "adequate basis for reasonably concluding that [all of the] compositions included by the claims would behave in the same manner as the . . . test compositions[s]." *In re Lindner*, 457 F.2d 506, 173 USPQ 356 (CCPA 1972). "[Applicant] is not required to test each and every species within the scope of the appealed claims and compare same with the closest prior art species. Rather, patentability is established by a showing of unexpected superiority for representative compounds within the scope of the appealed claims." *Ex parte Winters*, 11 USPQ2d 1387 (BPAI 1988). As such, the claims in this case are commensurate in scope with the experiments conducted in the declaration and such evidence overcomes any obviousness.

In summary, the present invention claims various anti-microbial compositions and formulations. Trinh simply does not teach or render obvious the claimed anti-microbial

composition. Namely, Trinh does not teach the inclusion of the low surface tension material used in the claimed composition. For at least this reason, the Examiner has not established a *prima facie* case of obviousness. Even if this Board should consider the *prima facie* case to have been established, Applicant has provided substantial evidence showing the surprising and unexpected benefits of the present invention, indicating that the invention would not be considered obvious in light of Trinh. Thus, it is respectfully requested that Applicant's Appeal be granted and a patent issue based on the above-captioned application.

Respectfully requested,
NELSON MULLINS RILEY & SCARBOROUGH

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